National Eye Institute (NEI)/National Institutes of Health (NIH): Age-Related Eye Disease Study: Women Interagency HIV Study (WIHS)

AREDS investigators reported on clinical trial findings that a daily, high-dose combination of antioxidant vitamins C, E, and beta-carotene, and the trace element zinc reduced the risk of developing advanced AMD by 25% over a five-year period.

Lead Agency:

National Eye Institute (NEI)

National Institutes of Health (NIH)

Agency Mission:

The National Eye Institute (NEI) was established by Congress in 1968 to protect and prolong the vision of the American people. As one of the Federal government's National Institutes of Health (NIH), the NEI conducts and supports research that helps prevent and treat eye diseases and other disorders of vision. This research leads to sight-saving treatments, reduces visual impairment and blindness, and improves the quality of life for people of all ages. NEI-supported research has advanced our knowledge of how the visual system functions in health and disease.

Principal Investigators:

Dr. Frederick Ferris

Address: 10-CRC - Hatfield Clinical Research Center, 3-2531

10 Center Drive Bethesda, MD 20892

General Description:

Age-Related Eye Disease Study (AREDS)

The two most common eye diseases associated with aging are lens opacities (cataract), a leading cause of worldwide blindness, and age-related macular degeneration (AMD), the leading cause of irreversible vision loss in the United States among persons over 65 years of age. Cataract surgery replaces the opaque, natural lens with a clear, synthetic lens and is highly successful in the United States. However, in developing countries, the procedure is costly and not readily available. There are no cures for AMD, which causes the loss of light sensing photoreceptor cells in the central portion of the retina (macula) that provides us with sharp visual acuity and color vision. In the initial phases of the disease, patients experience trouble reading fine print and seeing in dim light. During the advanced stages, the disease destroys the macula, resulting in severe vision loss and legal blindness. Patients with advanced AMD can no longer read, recognize faces, drive a car, or perform simple daily tasks that require hand-eye coordination. AMD greatly diminishes mobility, independence and the quality of life. A delay in the progression of AMD would provide improved visual function for afflicted individuals. As the US population ages, the

prevalence of AMD and cataracts is expected to rise sharply, placing ever greater burdens on healthcare and social services.

The NEI initiated the Age-Related Eye Disease Study (AREDS) to evaluate, in part, the effects of antioxidants on the development and progression of AMD and cataracts. AREDS included a large, multi-center clinical trial involving 4,757 participants, 55 to 80 years of age, in 11 clinical centers nationwide. Researchers found that people at high risk of developing advanced stages of AMD lowered their risk of progression by about 25 percent over a five-year period when treated with a daily, high-dose combination of antioxidant vitamins C, E, and beta-carotene, and the trace element zinc. No effect of these nutrients on cataract formation was observed. This nutritional therapy represents the first treatment to slow the progression of AMD and delay the onset of severe and debilitating vision loss. Based on published prevalence data, an estimated 8 million Americans at least 55 years old are at high risk to develop advanced AMD. Based on results from the AREDS, 1.3 million of these people would develop advanced AMD over the next five years if no treatment were given to reduce their risk. If this at-risk population avails themselves of the AREDS nutritional formulation (vitamins C, E, betacarotene, and zinc), greater than 300,000 would avoid advanced AMD and its associated vision loss over the next five years.

AREDS also added to our understanding of the epidemiology of AMD and cataract. Data from AREDS and other studies suggested that lutein/zeaxanthin and omega-3 long chain polyunsaturated fatty acids might also have benefit in AMD and cataract. Leveraging these findings, NEI began AREDS 2 in 2005, a multicenter study that will include up to 100 clinical sites to evaluate these supplements and other modifications of the original AREDS formulations on AMD and cataract.

Women Interagency HIV Study (WIHS)

The Women's Interagency HIV Study (WIHS) was established in August 1993 to investigate the impact of HIV infection on women in the United States. Approximately 3,700 women have been enrolled, of which 2,400 are still attending visits every six months (the remaining have either died or lost to follow-up). The core portion of this NIH-supported study includes a detailed and structured interview, physical and gynecologic examinations, and laboratory testing. The WIHS participants are also asked to enroll in various sub-studies, including cardiovascular, metabolic, and physical functioning.

Excellence: What makes this project exceptional?

AREDS offers the first treatment to slow the progression of AMD.

Significance: How is this research relevant to older persons, populations and/or an aging society?

AMD is the leading cause of blindness in older Americans in the United States.

Effectiveness: What is the impact and/or application of this research to older persons?

If the more than 8 million older Americans at high risk of developing advanced AMD took the AREDS formulation, more than 300,000 would avoid severe vision loss over the next 5 years.

Innovativeness: Why is this exciting or newsworthy?

AREDS offers a valuable therapy to prevent severe vision loss simply by taking a relatively low-cost antioxidant supplement.